K132445

DEC - 6 2013

PIEZON 250
Special 510(k): Device Modification
510(k) Summary
(per 21 CFR 807.92(c))

1. SUBMITTER/510(K) HOLDER

E.M.S. ELECTRO MEDICAL SYSTEMS S.A.
Ch. de la Vuarpillière 31
CH - 1260 Nyon
Switzerland

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Date Prepared: August 2, 2013

2. DEVICE NAME

Proprietary Name:	PIEZON 250
Common/Usual Name:	Ultrasonic Scaler
Classification Name:	Ultrasonic Scaler (21 CFR 872.4850, Product Code ELC)

3. PREDICATE DEVICES

The proposed PIEZON 250 is a modification of the E.M.S. ELECTRO MEDICAL SYSTEMS S.A., miniPiezon (K953026).

The Piezon handpiece LED that is compatible with the proposed device was described in the 510(k) premarket notification for the Piezon Master 700 (K093000).

The instruments used with the PIEZON 250 were previously cleared for E.M.S.ELECTRO MEDICAL SYSTEMS S.A:

- miniMaster Ultrasonic Scaler (K050710)
- EMS Kermit (K992504)
- miniPiezon (K953026)
- Piezon Master 400 (K896749)
- Piezon Master 600 (K022328)
- Piezon Master 700 (K093000)

4. DEVICE DESCRIPTION

The proposed PIEZON 250 ultrasonic scaler is a modification of the previously cleared miniPiezon (K953026). The working instrument for the scaling function is the handpiece, which is connected to the control unit via a handpiece cord and mounted in a holder on the side of the control unit.

In the proposed PIEZON 250, irrigating liquid is pumped to the handpiece from a 350ml (or 500ml) irrigating bottle by a peristaltic pump rather than from an external water supply. The flow rate of the irrigating liquid is adjusted via a rotating knob located on the side of the control unit.

The PIEZON 250 is supplied with two handpieces – the Piezon handpiece LED (light-emitting diode) and the Piezon handpiece. The Piezon handpiece LED is identical to the Piezon handpiece LED described in K093000 for the Piezon Master 700 ultrasonic scaler (K093000) and contains 6 LEDs in the body of the handpiece and a light guide that is positioned under the nozzle. The Piezon handpiece is identical to the Piezon handpiece LED, except that the Piezon handpiece does not have LEDs or the light guide. All instruments compatible with the PIEZON 250 have been previously cleared (see 510(k) numbers referenced in Section 3).

The modifications made to the miniPiezon to produce the PIEZON 250 include:

- Shape and contours of the control unit redesigned to accommodate the finger-tip power control, improve aesthetics, facilitate cleaning, and enhance ergonomics
- Use of a potentiometer for power regulation via the power control knob to improve ultrasonic power control.
- One operating mode with a Standard power range (0-100% power) for scaling procedures and a Perio range (0-37.5% power) for periodontal procedures
- Supported handpieces (Piezon handpiece (FT-215#) and Piezon handpiece LED (FT-223#)
- Ultrasonic generator upgraded to EJ-110. In EJ-110, the Light command, Motor/Solenoid valve command and Pedal command have been added.
- Replacement of external water supply connection with an irrigating liquid bottle to supply irrigant to the handpiece via a peristaltic pump

5. INTENDED USE

The PIEZON 250 is a device for delivering ultrasonic movement and irrigant to a stainless steel tip which is used by a dentist or dental hygienist. The indications for use are:

- Periodontal pocket lavage with simultaneous ultrasonic tip movement
- Scaling and root planing
- Removal of supra and subgingival calculus and stains from teeth

6. Summary of Technological Characteristics Compared to the Predicate Devices

The proposed PIEZON 250 is similar in design and materials to the parent miniPiezon. Both the proposed and parent devices are ultrasonic scalers consisting of a control unit housing an ultrasonic generator that produces piezo-electric vibrations to perform the scaling function. The working instrument for both the proposed and predicate devices is the handpiece, which is connected to a control unit via a handpiece cord. A scaling instrument specific to a particular scaling procedure is attached to the end of the handpiece.

Unlike the predicate miniPiezon, the proposed PIEZON 250 does not have a connection to an external water supply. Instead, the proposed PIEZON 250 contains an irrigating liquid bottle that is mounted at the back of the control unit which supplies irrigating liquid to the connected handpiece via a peristaltic pump. The overall design of the irrigant delivery system for the PIEZON 250, including the peristaltic pump and the compatible irrigation solutions, is identical to that of the predicate Piezon Master 700 with the exception that the Piezon Master 700 allows the user to choose between two irrigating liquid bottles.

Differences between the proposed PIEZON 250 and the predicate miniPiezon and Piezon Master 700 are limited to the irrigant delivery system, compatible handpieces, and the control unit modifications to improve ergonomics and ultrasonic power control described in Section 4. The similarities and differences between the proposed and parent devices are illustrated in the table at the end of this section.

7. Summary of Non-Clinical Performance Testing as Basis for Substantial Equivalence

Non-clinical performance testing demonstrates that all design inputs for the PIEZON 250 were satisfied by the design outputs, that the device meets electrical safety and electromagnetic compatibility requirements, and functional and performance requirements. The similarities in intended use, operational characteristics, and functional technological characteristics between the proposed PIEZON 250 and the parent miniPiezon and predicate Piezon Master 700 lead to a conclusion of substantial equivalence between the proposed and predicate devices.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted for this submission.

9. SUMMARY OF OTHER INFORMATION

No other information is available.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

The similarities in intended use, operational characteristics, and functional technological characteristics between the proposed PIEZON 250 and the predicate miniPiezon lead to a conclusion of substantial equivalence between the proposed and predicate devices. A side-by-side comparison of the predicate devices and the proposed device is provided in the table below.

Comparison Table for Determination of Substantial Equivalence

Item for Comparison	PIEZON 250 (FT-216#) Piezon handpiece Proposed	PIEZON 250 (FT-224#) Piezon handpiece LED Proposed	Piezon Master 700 K093000	EMS miniPiezon K953026
Indications for Use	Intended for use in dental and periodontal applications performed by an ultrasonic scaler.	Intended for use in dental and periodontal applications performed by an ultrasonic scaler.	Intended for use in dental and periodontal applications performed by an ultrasonic scaler.	Intended for use in dental and periodontal applications performed by an ultrasonic scaler.
Treatment Site	Subgingival and supragingival	Subgingival and supragingival	Subgingival and supragingival	Subgingival and supragingival
Function	Ultrasonic scaling	Ultrasonic scaling	Ultrasonic scaling	Ultrasonic scaling
Mechanism of action	Ultrasonic energy	Ultrasonic energy	Ultrasonic energy	Ultrasonic energy
Components	• Control Unit • Foot pedal • Piezon handpiece* • Instruments+ • Irrigating liquid bottle	• Control Unit • Foot pedal • Piezon handpiece* LED • Instruments+ • Irrigating liquid bottle	• Control Unit • Foot pedal • Piezon handpiece LED • Instruments+ • Irrigating liquid bottle	• Control Unit • Foot pedal • Universal Piezon handpiece • Instruments+ • Water hose with quick connector on device

*Previously cleared in K093000
+All instruments previously cleared (see Section 3)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 6, 2013

E.M.S. Electro Medical Systems S.A.
C/O Cynthia J.M. Nolte
Director, Medical Device Regulatory Services
AptivSolutions
62 Forest Street. Suite 300
Marlborough, MA 01752

Re: K132445
Trade/Device Name: PIEZON 250
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: October 25, 2013
Received: November 6, 2013

Dear Ms. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. for
Ulmer -S

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132445

Device Name: PIEZON 250

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner DDS, MA

Mary S. Runner -S
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